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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/760,046	01/12/2001	Edith Mathiowitz	BU 111	1885

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EXAMINER

PULLIAM, AMY E

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 12/02/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/760,046

Applicant(s)

MATHIOWITZ ET AL.

Examiner

Amy E Pulliam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,6-13,15-26 and 34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,6-13,15-26 and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

Receipt of Papers

Receipt is acknowledged of the Request for Extension of Time and Request for Continued Examination, both received by the Office April 9, 2003, as well as the Preliminary Amendment D, received May 9, 2003.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 7-9, 11-13, 15-17, 19, and 23-26 rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/46212 to Shah.

Shah teach a method for making a composition comprising an active ingredient contained within polymeric microparticles, wherein a mixture of the active ingredient and the polymer are dispersed within a continuous phase, the resulting dispersion is frozen, and the water and organic solvents are removed from the dispersion by lyophilization (page 28, claim 1). Claim 4 states that the active is dissolved in a non-aqueous solvent prior to addition to the continuous phase. The reference also teaches that spray drying, solvent evaporation, phase separate techniques and that they are all well known in the art as encapsulation methods (page 4, lines 17-20). It is the position of the examiner that the teachings of Shah anticipate the above listed claims.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, 4, 6-13, 15-26, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shah.

Shah is discussed above as teachings Applicant's claimed method. Shah does not specifically state that the particles are micronized in the step where the emulsion is formed. However, Shah does teach the same process as claimed by Applicant, and Shah does not teach an additional grinding or milling step to micronize the particles. Therefore, the micronization must occur at the same time in the reference.

Furthermore, Shah does not teach the particular particle size. However, it is the position of the examiner that this does not render patentable distinction to the claims for two reasons. First, Shah teaches the same process and therefore the product will have the same characteristics. Alternatively, absent a clear showing of criticality, the determination of a particular particle size is within the skill of the ordinary worker as part of the process of normal optimization.

Shah also lacks the teaching to the specific active found in Applicant's claim 10. It is the position of the examiner that one of ordinary skill in the art would use any well known protein in the teachings of Shah, because Shah teaches success with proteins in general.

Shah also lacks the teaching of particular ranges of solvent to non-solvent. Again the examiner does not find that this renders patentable distinction to the claims. First, the Office

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lacks the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. *See Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977). Second, absent a clear showing of criticality, the determination of a particular ratio is within the skill of the ordinary worker as part of the process of normal optimization. Any showing of criticality must be based upon this particular limitation alone.

Therefore, it is the position of the examiner that the teachings of Shah suggest the limitations of Applicant's instant claims. Shah teaches the same process of making microparticles, and one skilled in the art would have been motivated to use any well known protein, and to manipulate the particle size and the ratios of the process components, depending on the particular active and the desired end product. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive. Applicant argues that Shah does not teach the particles size of the protein particles. The examiner agrees with this statement, as it was clearly discussed in the rejection of the last office action. However,

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as was also stated in the last office action, the examiner maintains that, absent evidence to the contrary, the determination of a particular particle size is manipulatable as part of the process of normal optimization.

Applicant also argues that Shah requires an extra step, in making a double emulsion. This argument is not found persuasive as Applicant's claims use comprising language, and therefore do not prohibit the presence of additional steps.

Lastly, Applicant argues that Shah does not teach the separation step, requiring the separation of the active agent from the macromolecular material. It is unclear to the examiner what the unexpected result attained by this step is. More specifically, Applicant states that Shah teaches an encapsulation process. However, as clearly evidenced by the specification and instant claims, Applicant is also teaching an encapsulation process. Claim 2 specifically includes an encapsulation step, and claim 1 does not exclude the presence of such a step. Furthermore, it appears that the process of Shah and the process of Applicant result in the same product. Therefore, the only difference appears to be that Applicant requires an additional step to achieve the same product. Applicant is invited to more clearly explain the presence of the separation step in the response to the action. Until then, the current rejections are maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A.E. Pulliam
Patent Examiner
Art Unit 1615
November 28, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600